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Kent
Imaging Inc

AUG 8 2012

510(k) Summary

Kent Camera (November 21, 2011)

Submittal Information:

Post-approval contact:
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Kent Imaging Inc.
804-B, 16th Avenue SW
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Phone: 403-455-7611
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Device and Classification Name

Proprietary Name:	Kent Camera
Common Name:	Tissue Oximeter
Classification Name:	Oximeter, Tissue Saturation (21 CFR 870.2700, Product Code: 74 MUD)

Substantial Equivalence

The Kent Camera is substantially equivalent to the OxyVu-1 Hyperspectral Tissue Oxygenation Measurement System manufactured by Hypermed, Inc. The OxyVu-1 system was cleared in 510(k)s K061848 and K073656.

Device Description

The Kent Camera is based on multispectral imaging technology and performs spectral analysis at each point in a two-dimensional scanned area producing an image displaying information derived from the analysis. The Kent Camera determines the approximate values of oxygen saturation (StO_2), oxyhemoglobin levels (HbO_2), and deoxyhemoglobin levels (Hb) in superficial tissues and displays a two-dimensional, color-coded image of the tissue oxygenation (StO_2).

The device consists of:

Imaging Head: Contains light sources, camera, and spectral filters for collecting image data.

Touchscreen Computer: User interface, display of images, and image data processing.

Cart: Support and attachment points for imaging head and touchscreen computer.

Intended Use

The Kent Camera is intended for use by healthcare professionals as a non-invasive tissue oxygenation measurement system that reports an approximate value of:

- oxygen saturation (StO_2),

- oxyhemoglobin level (HbO_2), and
- deoxyhemoglobin (Hb) level

in superficial tissue. The Kent Camera displays two-dimensional color-coded images of tissue oxygenation of the scanned surface and reports multispectral tissue oxygenation measurements for selected tissue regions.

The Kent Camera is indicated for use to determine oxygenation levels in superficial tissues for patients with potential circulatory compromise.

Comparison with the Predicate Device

Comparative Feature	Kent Imaging Inc. "Kent Camera"	Hypermed Inc. "OxyVu-1"
Measurements	Same	• Oxygen saturation • Oxyhemoglobin level • Deoxyhemoglobin level
Method of Measurement	Same	Spectral analysis at specific wavelengths of light returned from target tissue.
Output Display	Same	• Two-dimensional color-coded map (image) of estimated oxygen saturation • Numeric data
Patient Contact	None	Uses a disposable "Target Pad" placed on the patient near the area of interest

Similarities and Differences

Both devices use spectral analysis to determine oxygenation levels in near-surface tissues. Both devices display numeric values of approximate oxygen saturation of the hemoglobin as well as displaying the related approximate oxyhemoglobin and deoxyhemoglobin levels necessary for the oxygen saturation calculation. Both devices provide two-dimensional mapping of color-coded oxygenation levels.

The Kent Camera does not use any patient contacting components or accessories. The OxyVu-1 uses a disposable "Target Pad" accessory that contacts the patient near the area of interest.

Basis of Substantial Equivalence

Based on equivalent intended uses and technologies and results from performance testing, the Kent Camera is substantially equivalent to the OxyVu-1 Hyperspectral Tissue Oxygenation Measurement System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 8 2012

Kent Imaging Inc.
c/o Mr. Darrell Barnhart
Vice President
1440, 720 – 13th Avenue SW
Calgary, Alberta
Canada, T2R 1M5

Re: K113507
Trade/Device Name: Kent Camera
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter, tissue saturation
Regulatory Class: Class II (two)
Product Code: MUD
Dated: June 8, 2012
Received: June 11, 2012

Dear Mr. Barnhart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: Kent Camera

Indications For Use:

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- oxygen saturation (StO_2),
- oxyhemoglobin level (HbO_2), and
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in superficial tissue. The Kent Camera displays two-dimensional color-coded images of tissue oxygenation of the scanned surface and reports multispectral tissue oxygenation measurements for selected tissue regions..

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113507